

R.1.26

3/9/06 *amdt*

USSN: 10/501,606  
Atty. Dkt. No.: PP018892.0003  
2300-18892

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (currently amended): A composition suitable for mucosal delivery comprising an HIV envelope antigen and a detoxified mutant A subunit of *E. coli* heat labile toxin (LT) selected from one or more of the group consisting of LTK63 and LTR72, wherein said HIV envelope antigen is in an amount of about 0.1  $\mu$ g to about 1000  $\mu$ g.

2. (original): The composition of claim 1, wherein said heat labile toxin is LTK63.

3. (withdrawn): The composition of claim 1, wherein said heat labile toxin is LTR72.

4. (original): The composition of claim 1, wherein said toxin comprises a holotoxin of said *E. coli* heat labile toxin.

5. (currently amended): The composition of claim 1, wherein said envelope antigen ~~protein~~ is selected from the group consisting of gp120, gp160 and ~~gp140~~ Ogp140.

6. (original): The composition of claim 1, wherein said HIV envelope antigen is optimized for immunogenicity.

7. (original): The composition of claim 1, wherein said composition further comprises a second HIV antigen.

8. (original): The composition of claim 7, wherein said second HIV antigen is optimized for immunogenicity.

9. (original): The composition of claim 7, wherein said second HIV antigen is selected from one or more of the group consisting of HIV structural proteins, HIV regulatory proteins, and HIV accessory proteins.

10. (original): The composition of claim 9, wherein said HIV structural protein is selected from the group consisting of Gag, Pol and envelope.

11. (original): The composition of claim 9, wherein said HIV regulatory protein is selected from the group consisting of Tat and Rev.

12. (original): The composition of claim 9, wherein said HIV accessory protein is selected from the group consisting of Vpu, Vpr, Vif, and Nef.

13. (original): The composition of claim 10, wherein said second HIV antigen is gag.

14. (original): The composition of claim 1, wherein said composition is suitable for intranasal delivery.

15. (original): The composition of claim 1, wherein said composition is suitable for intra-vaginal delivery.

16. (original): The composition of claim 1, wherein said composition is suitable for intra-rectal delivery.

17. (withdrawn - currently amended): A composition suitable for mucosal delivery comprising a polynucleotide encoding for an HIV envelope protein and a detoxified mutant A subunit of E. coli heat labile toxin (LT) selected from one or more of the group consisting of LTK63 and LTR72, wherein said HIV envelope protein is in an amount of about 0.1 µg to about 1000 µg.

18. (withdrawn - currently amended): A composition suitable for mucosal delivery comprising an HIV envelope protein and a polynucleotide encoding a detoxified mutant A subunit of *E. coli* heat labile toxin (LT) selected from one or more of the group consisting of LTK63 and LTR72, wherein said HIV envelope protein is in an amount of about 0.1  $\mu$ g to about 1000  $\mu$ g.

19. (withdrawn - currently amended): A method for raising an immune response in a subject comprising mucosally administering to the subject a composition comprising an HIV envelope antigen and a detoxified mutant A subunit of *E. coli* heat labile toxin (LT) selected from the group consisting of LTK63 and LTR72, wherein said HIV envelope antigen is in an amount of about 0.1  $\mu$ g to about 1000  $\mu$ g.

20. (withdrawn): The method of claim 19, wherein said heat labile toxin is LTK63.

21. (withdrawn): The method of claim 19, wherein said heat labile toxin is LTR72.

22. (withdrawn): The method of claim 19, wherein said toxin comprises a holotoxin of said *E. coli* heat labile toxin.

23. (withdrawn - currently amended): The method of claim 19, wherein said envelope antigen protein is selected from the group consisting of gp120, gp160 and ~~gp140~~ Ogp140.

24. (withdrawn): The method of claim 19, further comprising administering a second HIV antigen.

25. (withdrawn): The method of claim 24, wherein said second HIV antigen is selected from one or more of the group consisting of HIV structural proteins, HIV regulatory proteins, and HIV accessory proteins.

26. (withdrawn): The method of claim 24, wherein said second HIV antigen is gag.

27. (withdrawn): The method of claim 17 wherein said composition is administered intranasally.

26. (withdrawn): The method of claim 19, wherein said composition is administered intravaginally.

27. (withdrawn): The method of claim 19, wherein said composition is administered intrarectally.

28. (withdrawn - currently amended): A method for raising an immune response in a subject comprising mucosally administering to the subject a composition comprising a polynucleotide encoding an HIV envelope antigen and a detoxified mutant A subunit of *E. coli* heat labile toxin (LT) selected from the group consisting of LTK63 and LTR72, wherein said HIV envelope antigen is in an amount of about 0.1  $\mu$ g to about 1000  $\mu$ g.

29. (withdrawn - currently amended): A method for raising an immune response in a subject comprising mucosally administering to the subject a composition comprising an HIV envelope antigen and a polynucleotide encoding a detoxified mutant A subunit of *E. coli* heat labile toxin (LT) selected from the group consisting of LTK63 and LTR72, wherein said HIV envelope antigen is in an amount of about 0.1  $\mu$ g to about 1000  $\mu$ g.

30. (new): The composition of claim 1, wherein said HIV envelope antigen is in an amount of about 1  $\mu$ g to about 300  $\mu$ g.

31. (new): The composition of claim 30, wherein said HIV envelope antigen is in an amount of about 100  $\mu$ g.

32. (new): The composition of claim 1, wherein said HIV envelope antigen is in an amount of about 100  $\mu$ g.

33. (new): The composition of claim 5, wherein said envelope antigen is Ogp140 in an amount of about 300  $\mu\text{g}$ .

34. (new): The composition of claim 5, wherein said Ogp140 comprises an arginine to serine substitution in the primary protease cleavage site (REKR).

35. (new): The composition of claim 17, wherein said HIV envelope protein is in an amount of about 1  $\mu\text{g}$  to about 300  $\mu\text{g}$ .

36. (new): The composition of claim 18, wherein HIV envelope protein is in an amount of about 1  $\mu\text{g}$  to about 300  $\mu\text{g}$ .

37. (new): The method of claim 28, wherein said HIV envelope antigen is in an amount of about 0.1  $\mu\text{g}$  to about 1000  $\mu\text{g}$ .

38. (new): The method of claim 29, wherein said HIV envelope antigen is in an amount of about 1  $\mu\text{g}$  to about 300  $\mu\text{g}$ .